Acclusal and skeletal effects of an oral appliance in the treatment of obsructive sleep apnea

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[Headnote]

Occlusal and Skeletal Effects of an Oral Appliance in the Treatment of Obstructive Sleep Apnea*

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Study objectives: Oral appliances (OAs) are considered to be a treatment option for patients with obstructive sleep apnea/hypopnea syndrome (OSAHS). Although the effectiveness of these appliances has been evaluated in a number of clinical trials, there are few follow-up studies concerning the dental and skeletal side effects that, theoretically, could be caused by OAs. We sought to examine the long-term skeletal and occlusal effects of a nocturnally worn activator in adult patients treated for OSAHS.

Design: We analyzed the dental casts and lateral radiographs of 34 patients (mean age, 52.9 years; SD, 9.6 years; range, 27.1 to 64.6 years) before initiating treatment and after at least 24 months of treatment (mean length of treatment, 29.6 months; range, 24.1 to 43.5 months; SD, 5.1 months). The OA was worn by each patient 6 to 8 h nightly for > 5 days per week.

Setting: Department of Orthodontics, Dental Medical School, Freiburg, Germany.

Measurements and results: Follow-up polysomnography studies confirmed improved breathing parameters with the use of OAs. A statistically significant alteration in the occlusion was found. The anteroposterior position of the molars and the inclination of the upper and lower incisors were changed. No skeletal changes in the position of the mandible were noted.

Conclusions: The data suggest that in addition to control polysomnographic examinations, regular dental follow-up visits are mandatory when lifelong OSAHS treatment with an OA is being considered for patients with obstructive sleep apnea/hypopnea.

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[Headnote]

Key words: mandibular advancement devices; oral appliances; side effects; sleep apnea; snoring; treatment

[Headnote]

Abbreviations: CPAP = continuous positive airway pressure; OA = oral appliance; OSAHS = obstructive sleep apnea/hypopnea syndrome

Obstructive sleep apnea/hypopnea syndrome (OSAHS) is caused by the periodic reduction or cessation of airflow due to narrowing or occlusion of the upper airway during sleep. Continuous positive airway pressure (CPAP) therapy is indicated when the respiratory disturbance index exceeds 30 events per hour. A respiratory disturbance index of > 5 events per hour should be considered for treatment if it is associated with typical clinical symptoms like daytime sleepiness and/or cardiovascular disease.1 A recently published study2 has suggested an elevated risk of developing cardiovascular disease even when sleep-related breathing disorders of low intensity are present. Accordingly, treatment might even be indicated in nonsleepy patients with mild nocturnal apneas/hypopneas.3 In several studies,4,5 oral appliances (OAs) have been shown to improve OSAHS symptoms and objectively measured breathing parameters in selected obstructive sleep apnea patients and are considered to be an additional treatment approach. In these patients, especially in young patients with mild OSAHS, compliance might be higher with OA therapy than with conventional CPAP therapy.6,7

For the most part, the design of OAs is derived from functional orthodontic devices. To maintain the patency of the pharyngeal airway and to prevent the lumen from collapsing during sleep,8,9 the appliances hold the mandible in a forward and vertically opened position. OAs are anchored mainly on the dentition rather than the mucosa to ensure retention, thus, the teeth are loaded with permanent forces when the device is worn at night.10,11

Patients with OSAHS treated by OAs need to use the device on a long-term basis to prevent the recurrence of symptoms. It is thus important to clarify the potential adverse effects of OA treatment on the dentition, occlusion, and skeletal changes in adults after long-term nocturnal use of the OAs over a period of at least 24 months.

MATERIALS AND METHODS

We retrospectively analyzed the **dental** casts and lateral head plates taken before the start of **treatment** and thereafter at a mean of 29.6 months (SD, 5.1 months; range, 24.1 to 43.5 months). Thirty-four otherwise healthy patients with mild-- to-moderate OSAHS were enrolled in the study. The patients' ages ranged from 27.1 to 64.6 years (mean age, 52.9 years; SD, 9.6 years), and the mean body mass index was increased at 28.6 kg/m^sup 2^ (SD, 4.2 kg/m^sup 2^). The diagnosis and the degree of severity of obstructive sleep apnea were established by polysomnography. The patients either did not tolerate CPAP and/or they refused to use it on a long-term basis. They were therefore offered OA **treatment** instead. According to our **treatment** regime, patients were treated with an OA and were included in this follow-up **analysis** if the success of their **treatment** with an OA had been confirmed by control polysomnography that had been carried out 4 months (SD, 1.2) after the OA emplacement.

Only those patients were included into the study who had given us convincing assurance that the device had been worn on a regular basis for at least 6 to 8 h per night for > 5 nights per week during the study period. Patients with fewer than 10 healthy teeth in each jaw, or those with active **dental** or periodontal disease and/or severe temporomandibular joint dysfunction at the time of the baseline investigation were excluded from this long-term assessment. The patients accepted into the study were subjected to a standardized clinical and **dental** examination before **treatment** and at the follow-up appointment. These examinations included the use of lateral cephalometric radiography in habitual occlusion and **dental** cast **analysis**. The intermaxillary relationship between the upper and lower **dental** arches was recorded with a wax registration in full occlusion.

The typical design of the appliance12 that was used is shown in Figure 1. The device consists of maxillary and mandibular plates that are made of hard acrylic (Orthocryl; Dentaurum; Pforzheim, Germany) and are joined by U-shaped clasps, allowing a gradual mandibular adjustment of the protrusion. The protrusion and the opening of the bite were individually adjusted for each patient according to a construction bite. In the sagittal plane, the protrusion was about 4 to 6 mm, and in the vertical plane the protrusion was about 8 to 12 mm. The degree of adjustment of the appliance was controlled in the vertical plane between the first central incisors, and in the sagittal plane at the position of the first molar, using the patient's dental models.

Wherever therapeutic efficacy was assessed as not being optimal according to the results of a control polysomnography examination and the comfort perceived by the patients, we adjusted the OAs by 2 to 5 mm in the sagittal plane to obtain a larger degree of protrusion, and patients underwent repeat polysomnography after 4 to 10 weeks. In those cases, the last polysomnography was analyzed statistically.

Data Collection

Cephalometric Analysis: Cephalometry was carried out according to the standard technique with the patient in an upright position with the head fixed in a cephalostat with a film focus distance of 4 m and a midsagittal-to-film

distance of 0.1 m. A total for linear and angular measurements was recorded by an single orthodontist. Significant cephalometric radiograph landmarks and lines of reference are illustrated in Figure 2. The tracing of the radiographs is based on the Freiburg analysis13 and on a modified method by Bosch et al.14

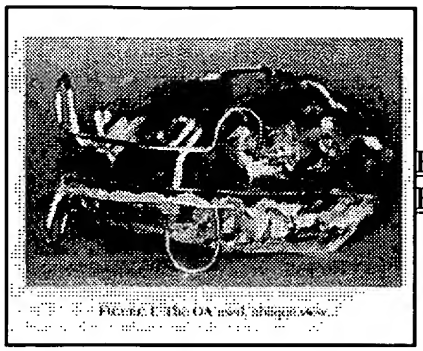

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FIGURE 1.

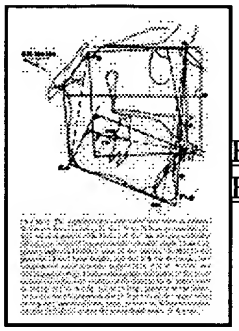

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FIGURE 2.

Study Cast Analysis: The maxillary and mandibular dental arch and occlusal relationships were analyzed manually from the dental study casts according to a standard previously published method15 using a sliding caliper with a resolution of 0.1 mm. A metric analysis of the arch form included the measurement of the anterior and posterior arch width, the anterior arch length, and the mesiodistal width of the lateral segments.16 The changes in the frontal segment were measured by determining the amount of overlap of the incisors or gaps, respectively. Frontal overjet, overbite, and the posterior overbite were assessed in full occlusion using the wax bite registration. The anteroposterior relationship was determined bilaterally according to the classification of Angle17 of malocclusion at the first molars and the canines on both sides.

Statistical Analysis

For variables measured on an ordinal scale, the Wilcoxon matched-pair signed rank was used to compare corresponding values at successive points in time. The level of significance was reduced according to the Bonferroni adjustment based on the number of comparisons to confirm the validity of significant results. The correlation between cephalometric and dental parameters and the variables of age, gender, duration of treatment, and data from the dental and skeletal assessment were analyzed using Spearman rank correlation coefficients. A value of $p < 0.05$ was considered to be statistically significant.

RESULTS

Polysomnographic data at baseline demonstrated the elevated respiratory parameters and sleep disturbance. In the follow-up registration, all patients benefited from the OA treatment and showed a reduction in the severity of the respiratory parameters. The apnea/ hypopnea index ($p < 0.001$) and the apnea index ($p < 0.001$) were significantly reduced, and the relative sleep architecture was unchanged, except the arousal index ($p < 0.01$). Polysomnographic data for the 34 patients are summarized in Table 1.

Subjective Side Effects

A total of 16 of 34 patients complained of discomfort and some side effects wearing the appliance. These included hypersalivation ($n = 4$), xerostomia ($n = 2$), temporomandibular joint pain ($n = 3$), pain or stiffness of the masseter muscle ($n = 6$), and tooth discomfort or pain ($n = 4$). These side effects were described by the patients as being of

minor intensity. On the day of the follow-up examination, such side effects had lessened and all patients reported being satisfied with the treatment. On being asked directly, two patients complained of occlusal changes, particularly in the posterior region. Thirty-two patients did not mention any occlusal alterations. None of the patients developed noises and/or crepitation in the temporomandibular joints.

Cephalonwtic Analysis

Table 2 summarizes the cephalometric findings at baseline and at the time point of the follow-up examination. Regarding the anteroposterior jaw relationship, 16 patients were skeletal class I, 11 patients were class II, and 7 patients were class III. In 17 patients, we found a dolichofacial morphology, in 9 patients we found a mesofacial morphology, and in 8 patients we found a brachyfacial morphology. The position of the mandible remained statistically unchanged. With regard to the cephalometric dental analysis, we found a significant alteration in the upper and lower incisor position relative to the craniofacial base and the mandibular plane, respectively. Overjet and overbite were significantly decreased. Furthermore, the upper incisors developed a significantly more lingual inclination, and the lower incisors developed a more labial inclination.

Dental Casts Analysis

The data of the measurements on the dental casts at baseline and at the follow-up examination are listed in Table 3. Overjet and frontal overbite were reduced significantly in the study cast analysis. A posterior open bite in the first molar region ($p < 0.001$) on both sides and a relative mesial shift of the mandible to the maxillary first molar ($p < 0.001$) had developed. The amount of anterior mandibular crowding was significantly reduced. A decrease in the overjet of > 1 mm occurred in nine patients (26%). A more anterior position of the lower molar of > 1 mm was found in eight patients (23.5%), and nine patients (26%) developed a posterior open bite.

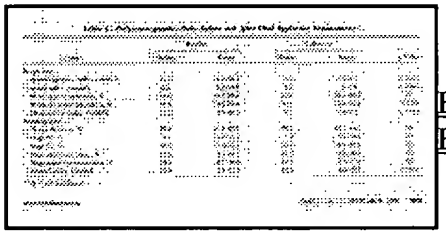

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Table 1

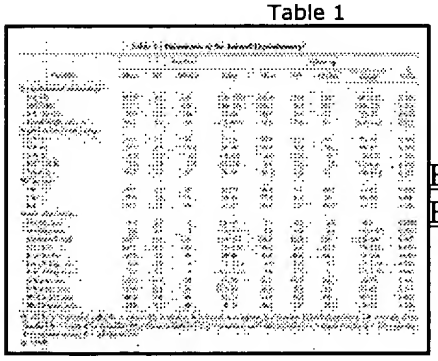

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Table 2

Method Error

Twenty cephalometic radiographs and study casts were analyzed to determine intraobserver method error on a second, separate occasion by the same investigator without knowledge of the respective results. No significant differences were found between the control and the original measurements using the paired Student t test. Method errors were determined by Dahlberg statistics18 and ranged from 0.2 deg to 0.5 deg and 0.2 to 0.6 mm, respectively, for angular and distance cephalometric measurements. This corresponds to ranges of coefficients of reliability from 0.94 to 0.98 and from 0.96 to 0.98, respectively. In the dental cast analysis, the method error ranged from 0.025 to 0.08 mm, corresponding to coefficients of reliability from 0.92 to 0.96.

Correlation Among General Variables

There was no significant correlation between age, gender, time of **treatment**, **dental** occlusion, and skeletal dentofacial pattern and the development of **dental** side effects determined in the cephalometric and plaster cast

analyses (r = -0.42; p = 0.0002).

DISCUSSION

With the growing use of OAs to treat OSAHS, it is important to define their long-term efficacy, compliance, and side effects. This study addresses the issue of long-term orthodontic side effects. In the present study, we found a more significant mesial anteriorposterior relationship in the dental occlusion, and changes in upper and lower incisors in patients who had been treated for OSAHS with a mandibular protrusive appliance for > 2 years. Overall, the changes observed were minor and clinically irrelevant, although in some cases they were quite pronounced and, thus, of clinical importance.

Our data also demonstrate that the OAs used are effective in reducing sleep-related breathing disturbances in the OSAHS patients who were selected (Table 1). In this investigation, we included only patients in whom the **treatment** success had been confirmed polysomnographically and by whom OA **treatment** was considered to be the **treatment** of choice. Possible **dental** side effects are a major concern when considering OA **treatment** in OSAHS patients. The data on this topic are conflicting. The meta-**analysis** by Schmidt-Nowara et al19 has suggested that oral discomfort is a common but tolerable side effect of OAs, and that **dental** and mandibular complications are uncommon. Pantin et al20 reported on minor or temporary **dental** side effects in patients who had worn OAs for a mean of 31 +/- 18 months. Nevertheless, they detected occlusal changes in 14% of their patients. Menn et al21 reported a 70% complication rate after 3.4 years of using OAs in a series of 29 patients. Unfortunately, they did not differentiate between oral discomfort and measurable changes in the **dental** situation. Irreversible changes in **dental** occlusion were reported in a case report study by Panula and Keski-- Nisula.22 In a recent evaluation23 of 22 patients treated with a removable mandibular advancement appliance, Fritsch et al23 also found a significant decrease in intermolar position and a decrease in overjet and overbite after 12 to 30 months.

OAs share similarities with functional orthodontic appliances in terms of their design, since they move the mandible into a protrusive and prefixed position.10,11 Due to this mechanism, the device generates reciprocal forces on the soft tissues and mandible. As the mandible attempts to return to its normal postural position during muscle relaxation, it can transmit a labially directed force against the mandibular incisors and a lingually directed force against the upper incisors. Our clinical investigation confirms this theoretical mechanism. We found a significant lingual tipping of the upper incisors and a labial tipping of the lower front teeth. The lingual tipping of the lower incisors explains our having noted a decrease in the anterior mandibular crowding and an elongation of the lower anterior arch in our patients. The upper labial bow in the activator used assists in guiding the appliance into a proper position. Although it is adjusted to not touch the teeth when the appliance is put into position, the wire nevertheless can often come into contact with the incisors during mandibular movement or the displacement of the device. This also may explain the lingual tipping of the upper incisors. The activator used has a loose fit, and the upper front teeth are not stabilized with acrylic. In order to reduce the transition of forces on the teeth, the occlusal surface might be covered with acrylic. However, occlusal changes have been seen even then.20,24,25 Fritsch et al23 described nearly the same dental side effects that we found in this study using an OA that fully covered both dental arches after a short investigation time. We therefore confirm, from the orthodontic point of view, their statement that the dental side effects observed are caused by the treatment factor protruding the mandible into an advanced position rather than by the design of the OA. As far as preventing dental side effects is concerned, one can speculate that temperature-sensitive acrylic material or soft elastomer might be preferable to the cold-cure acrylic resin used.26,27

We assume that the more frequent presence of a posterior open bite is caused by a more forward and downward posture of the mandible and/or by an intrusion of the posterior teeth.28 When acrylic is placed in contact with a tooth and the vertical dimension is opened past the normal postural position, the stretch of the soft tissue exerts an intrusive force on the teeth. The significantly open bite following 2 years' use of an OA with an extensive vertical opening of 8 to 12 mm might have reinforced the incidence of open bite in our cohort. An appliance with a less vertical opening and greater protrusion produces fewer intrusion forces. Statistically significant changes in the mandible posture were not confirmed in the cephalometric study, but in the dental cast analysis we noted a more mesial occlusal relationship, indicating a more forward position of the lower dental arch. A possible translocation of the mandible is obviously too minor to be detected by lateral cephalography. It still remains speculative as to what extent changes are being triggered by direct osseous adaptation in the temporomandibular joint, namely, the glenoid fossa. Precise examinations with CT or MRI scans are necessary to assess possible skeletal alterations.28

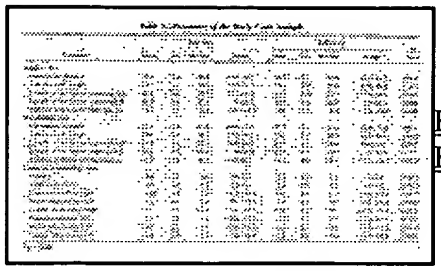

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Table 3

One shortcoming of our study, but also of other studies, is the absence of objective assessments of the exact length of time the OA has been worn by the patients At the beginning of the study, we had no such control equipment available. Therefore, we included only patients who convincingly reported that they had worn the appliance on a regular basis throughout the study period and in whom the inspection of the OA revealed signs of regular use. The intraoral recording of OA compliance remains complex and cannot be considered to be a standard method that is applicable to any type of OA.26 However, in future protocols, the registration of compliance indicating the time that the appliance has been worn may lead to even more reliable and objective data.

The patients enrolled in this study presented with healthy periodontal situations and with sufficient dental anchorage for the appliance. Since the incidence of OSAHS increases with age, elderly patients often demonstrate suboptimal dental conditions for placement of an OA, perhaps having lost teeth or having shown periodontal insufficiency. These factors are likely to lead to more side-effects. The present study suggests that there is a need for complete documentation of the dental situation, which should include dental casts, lateral cephalography, and intraoral photographic documentation, to enable a direct comparison of the occlusal status at baseline and during treatment.

CONCLUSION

Our findings show that OAs that advance the mandible in order to prevent OSAHS can cause significant dental side effects of differing degrees. These involve the inclination of the incisors and an alteration in the occlusal relationship to the mesial position. Once the medical indication for OA treatment has been determined by the sleep laboratory, somnographic control examinations are considered to be the standard means of assessing treatment effects. As demonstrated by our study, the dental situation also needs to be carefully checked during regular visits in order to recognize possible changes in the position of the teeth and of the occlusion. In particular, whenever these OAs are inserted into the mouths of patients with a simple snoring problem, the occlusal situation needs to be checked on a regular basis. Minor dental changes might be an acceptable side effect, if associated with significant treatment efficacy. In cases of unacceptable, progressive occlusal alterations, the indication for therapy with an OA has to be re-evaluated, and, in severe cases, therapy might have to be changed to CPAP.

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[Footnote]

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